

Via Express Mail
June 15, 2001

Dr. Brian Stanton
Biotechnology Practice Specialist
Group 1600
United States Patent Office
Washington, D.C. 20231

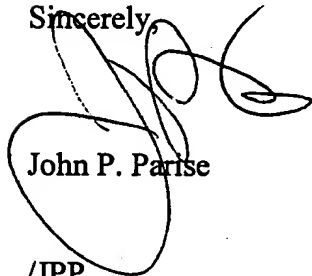
Re: U.S. Patent Application No. 08/711,339

Dear Dr. Stanton:

Further to my voice mail message and your June 14, 2001 telephone conversation with our Mr. William Epstein, I enclose a copy of my February 28, 2001 letter to Dr. Richard Schwartz, including the paperwork related to our March 27, 2000 Petition to Invoke the Supervisory Authority of the Commissioner Under 37 C.F.R. §1.181. I ask that you please follow-up on this patent application. Unfortunately, it has been almost fifteen months since we have heard from the Patent Office with respect to this patent application.

Thank you for any assistance you could provide.

Sincerely,


John P. Parise

/JPP

Enclosures

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CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being transmitted therewith) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

John P. Parise
(Print Name)

Date: March 27, 2000

(Signature)

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Binggeli et al

Group: 1613

Serial No. 08/711,339 filed September 6, 1996

Examiner: R. Ramseur

For: NOVEL PIPERIDINE DERIVATIVES HAVING RENIN INHIBITING
ACTIVITY

**PETITION TO INVOKE THE SUPERVISORY AUTHORITY OF THE
COMMISSIONER UNDER 37 C.F.R. §1.181**

Nutley, New Jersey 07110
March 27, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Petition to Invoke the Supervisory Authority of the Commissioner under 37 C.F.R. §1.181 is filed compel the Examiner to consider applicants' pending claims in their entirety. It is applicants' position that the Examiner has failed to follow both the law and Patent Office procedure, and this failure has

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caused applicants to be denied due process in having their claims considered. Authority for the filing of this Petition can be found 37 C.F.R. §1.181(a)(3).

Applicants request that this Petition be granted and that either (i) the application be returned to the Examiner with the requirement that the Examiner examine and consider on the merits all claims that read upon the elected species in their entirety or (ii) the application be returned to the Examiner with the requirement that the Examiner respond to applicants' Appeal Brief, dated February 22, 1999, so that the Board can address the issues.

Before addressing the facts and legal basis for the granting of this Petition, applicants wish to thank Dr. Richard A. Schwartz who has discussed this application with applicants' attorneys on several occasions, who was instrumental in having the application revived after being improperly abandoned by the Examiner, and who helped applicants with regard to moving this matter forward.

Statement of Facts

The subject application was filed on September 6, 1996. Claims 1-41 and 43-137 are pending. Claims 1-17, 20, 32, 33, 35-39, 42-45, 47, 68-72, 74, 77, 87-90 directly read upon the elected species. Claims 18, 19, 21-31, 34, 46, 48-67, 73, 75, 76, 79-86, and 91-136 do not read upon the elected species.

A first Office Action, dated October 17, 1997, stated that claim 1 "is generic to a plurality of disclosed patentably distinct species Applicant is required under 35 U.S.C. 121 to elect a single disclosed species Upoon [sic.] the election of a single disclosed species, a generic concept inclusive of the elected species will be determined by the Examiner for examination along with

the elected species." This Examiner-created "generic concept" is crux of the dispute described below.

Applicants responded to the October 17, 1997 Office Action by filing an Amendment, dated November 7, 1997, which stated

"In response to this election requirement, applicants request that the species claimed in new claim 137, i.e. (3R,4S,5S)-3-(1,4-dimethoxy-naphthalen-2-ylmethoxy)-4-[4-[3-(2-methoxy-benzyloxy)-propoxy]-phenyl]-piperidin-5-ol, (and supported in Example 112 - compound 11 and Example ZZ) be examined at this time. Applicants look forward to the species embodied by the compound of claim 137 being found patentable and to a further determination of patentability for the genus that includes this elected species, as embodied in claim 1."

In an Office Action dated March 23, 1998, the Examiner acknowledged that

"applicant has elected the species of claim 137 with traverse." The Examiner created a "generic concept as depicted in claim 1 where R¹ is aryl optionally substituted by lower alkyl, lower alkenyl, trifluoromethyl, lower alkoxy, hydroxy-lower alkoxy, alkoxy alkoxy, R² is phenyl or naphthyl each substituted by O-C₁₋₈ alkylene -O-C₁₋₈ alkylkene-aryl wherein aryl is as defined for R¹; X is O,S; Z is lower alkylene; Q is absent; m is O (W is absent); R³ is hydrogen; R⁴ is OH Claims 1-17, 20, 32, 33, 35-39, 42-45, 47, 68-72, 74, 77 and 87-90 are objected to as containing non-elected subject matter. The objection may be overcome by limiting the claim to the subject matter indicated as being examinable, supra. Claims so limited would appear allowable. Claims 40, 78 and 137, presented in independent form or made dependent on an allowable claim, would appear allowable."

In a Communication, dated July 16, 1998, applicants stated their position that

"the Patent Office does not have the legal authority or create a 'generic concept' and require applicants to limit a particular claim to the subject matter indicated as being allowable The Patent Office has failed to follow both its own internal procedures as set

forth in the MPEP and the law in making the restriction requirement and withdrawing the mentioned claims from consideration Procedures for making an election of species are described in MPEP 809.02. Applicants made a species election in response to this Office Action. As set forth in MPEP 809.02, the Patent Office is required to perform a search for all claims readable on the elected species The MPEP does not authorize the Patent Office to derive a 'generic concept as depicted in claim 1' to be carved out of existing claims. Therefore the Patent Office has not followed its own internal procedure."

The section of MPEP 803.02 citing *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 198 USPQ 334 (CCPA 1978) was brought to the Examiner's attention.

In an Office Action, dated September 25, 1998, the Examiner maintained the objection to the claims as set forth in the March 23, 1998 Office Action. As stated by the Examiner "The issue here is of restriction. 35 U.S.C. 121 gives the Commissioner the authority to restrict the examination to one invention." *In re Weber* and *In re Haas* was distinguished by the Examiner as allegedly being "involved in the rejection of claims under 35 U.S.C. 121 and the withdrawal of an entire claim."

In a Communication, dated December 22, 1998, applicants again argued that the "Patent Office has failed to follow both its own internal procedures as set forth in the MPEP and the law in making the restriction requirement and withdrawing the mentioned claims from consideration." Specifically, applicants argued that the Examiner did not follow MPEP 809.02 and that "restriction within a single claim cannot be sustained under 35 U.S.C. §121." "Withdrawal of applicants' claims, and in particular claim 1, from further

consideration due to an intraclaim restriction requirement amounts in fact to a rejection see *In re Haas*." Applicants simultaneously filed a Notice of Appeal.¹

An Appeal Brief, dated February 22, 1999, further supported the arguments that were made throughout the prosecution history.

In an Office Action, dated March 8, 1999, the Examiner announced "Prosecution on the merits is closed in accordance with the practice under *Ex Parte Quayle*." Also stated was "Failure to limit the claims to the elected subject matter may result in the abandonment of this application."

A Communication, dated May 5, 1999, stated "it is applicants' position that the Patent Office has in fact rejected all of the pending claims as a result of an improper restriction requirement. Future handling of this matter is now under consideration by the Board and the Group Director."²

A Notice of Abandonment, dated December 06, 1999, recited as a reason "Applicant's [sic.] failure to timely file a proper response to the Office Action of 3-8-99, i.e. to cancel the non elected subject matter."

Applicants contacted Dr. Richard A. Schwartz by telephone for the first time in late January concerning the Examiner's handling of this patent application. Dr. Schwartz informed applicants that their renewed petition had been denied and on February 10, 2000 (over two months after the Notice of

¹ Applicants also filed Petitions to have the restriction requirement withdrawn on November 11, 1998 and March 29, 1999. Both of these Petitions were denied. The question at issue in this Petition is whether the Patent Office followed the law and its own internal procedures in handling this application.

Abandonment) sent a facsimile copy of this Decision to applicants. Dr. Schwartz determined that the application had been improperly abandoned and had the application returned to pending status.

Applicants telephoned the Examiner to discuss the subject matter of this Petition. It was the Examiner's position that he would not consider claim 1 unless the claim were to be limited to the "generic concept" and that the Board could not review the application because there was no rejection to appeal. Applicants again telephoned Dr. Schwartz and were advised that the subject Petition would be applicants' most appropriate recourse.

Points to be Reviewed

- 1) Did the Examiner fail to follow Patent Office procedure as outlined in MPEP 809.02, *et seq.* when he asked for a species election and then, when provided with an elected species by applicants, created a "generic concept" instead of providing a complete action on the merits of all claims readable on the elected species?
- 2) Did the Examiner exceed his authority under 35 U.S.C. §121 when he created a "generic concept" inclusive of a species elected by applicants and required applicants to amend a single claim embracing the "generic concept" so as to only encompass the "generic concept" in order for that single claim to be examined and considered on the merits?

² The Examiner never responded to applicants' Appeal Brief. The Group Director eventually denied applicants' Renewed Petition. Dr. Schwartz sent the undated Group Director's Decision to applicants on February 10, 2000.

Arguments Relating to the Points to be Reviewed

The Examiner failed to follow Patent Office procedure as outlined in MPEP 809.02, *et seq.* when he asked for a species election and then, when provided with an elected species by applicants, created a "generic concept" instead of providing a complete action on the merits of all claims readable on the elected species.

MPEP 809.02 embraces the regulation set forth in 37 C.F.R. §1.146 which permits the Patent Office to "require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if **no claim to the genus is found allowable**" (emphasis added). MPEP 809.02(a) states that "Examiners should use Form Paragraphs 8.01 or 8.02 to make election requirements." MPEP 809.02(c) states "An examiner's action subsequent to an election of species should include **a complete action on the merits of all claims readable on the elected species**" (emphasis added).

The Examiner of the present application did not use Form Paragraphs 8.01 or 8.02 and failed to provide a complete action on the merits of all claims readable on the elected species. Rather, the Examiner created a "generic concept" which he examined without any action on the merits with respect to all claims that are readable on the elected species. The MPEP is clear as to what actions an Examiner should take. In the present application, the Examiner clearly failed to follow the procedure set forth in the MPEP by not using Form Paragraphs 8.01 or 8.02 and failing to provide a complete action on the merits of all claims readable on the elected species.

The Examiner exceeded his authority under 35 U.S.C. §121 when he created a "generic concept" inclusive of a species elected by applicants and required applicants to amend a single claim embracing the "generic concept" so as

to only encompass the "generic concept" in order for that single claim to be examined and considered on the merits. The Board of Patent Appeals and Interferences has jurisdiction to hear applicants' appeal because the claims have been effectively rejected by failure of the Patent Office to examine applicants' claims under the guise of restriction under 35 U.S.C. §121. Such refusal to examine applicants' claims is tantamount to a rejection and appealable. *In re Hass*, 179 USPQ 623 (CCPA 1973) ("*Hass I*").

"An examiner's adverse action of this nature is a rejection, a denial of substantive rights. Review thereof must fall within the jurisdiction of the board. *Hass I* at 627 (emphasis in original text).

The restriction requirement made by the Examiner was made solely under 35 U.S.C. §121 and should proceed as in *In re Hass*, 198 USPQ 335 (CCPA 1978) ("*Hass II*").

It is well-established law that restriction within a single claim cannot be sustained under 35 U.S.C. §121. As is stated in *In re Weber*, 198 U.S.P.Q. 328 (CCPA 1978) at pages 331-332,

"§121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It is not, however, provide a basis for the Examiner acting under the authority of the Commissioner to *reject a particular claim* on that same basis." (Emphasis in original text).

In the subject application, the Examiner made the exact type of restriction expressly forbidden by the CCPA in *In re Weber* (such restriction is tantamount to a rejection). There is no basis under 35 U.S.C. §121 for the Patent Office to

make an intraclaim restriction requirement of claim 1 and the subsequent generic claims encompassing the species of claim 137.

Nothing in 35 U.S.C. §121 gives the Examiner legal authority to create a "generic concept" and require applicants to amend a particular claim so as to only claim the subject matter indicated as being allowable, i.e. claim 1 as limited to embrace the "generic concept." Applicants have the right under U.S. patent law to claim their invention using the limitations that they regard as essential to delineate the invention, as long as the requirements of 35 U.S.C. §112 are met. See *In re Weber* at 331.

As in *Hass I*, the claims in the present application were withdrawn from consideration not only in this application but also prospectively in any subsequent application because of their content. As the Examiner's "generic concept" is constructed, it would be impossible for applicants to garner in subsequent patent applications the remainder of the claims after the "generic concept" is cleaved out, especially with regard to the written description requirement.

If the Examiner is permitted to create a "generic concept", numerous issues arise as to who is the inventor of the "generic concept"? and does the specification provide a written description of the "generic concept"? Although

every species contained within the "generic concept" would be enabled by the specification, the "generic concept" *per se* could lack a written description in the specification as filed. This is the exact situation envisioned in *In re Weber* which states on page 331:

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner rather than the applicant, it is not inconceivable that a number of the fragments would not be described by the specification.

Allowing the Examiner to proceed via a "generic concept" approach would be a disservice to all patent applicants and is not supported by the law. It is applicants' position that the Examiner must either allow or reject a claim that reads upon an elected species.

Action Requested

In view of the above, applicants request that this Petition be granted and that the subject application be remanded to the Examiner with the instruction to consider on the merits the entirety of claims 1-17, 20, 32, 33, 35-39, 42-45, 47, 68-72, 74, 77, 87-90, and if claim 1 is deemed patentable, then to consider on the merits claims 18, 19, 21-31, 34, 46, 48-67, 73, 75, 76, 79-86, and 91-136. Alternatively, applicants request the application be returned to the Examiner with the requirement that the Examiner respond to applicants' Appeal Brief, dated February 22, 1999, so that the Board can address the issues.

No fee is required in connection with the filing of this Petition. If any fee is deemed necessary, applicants authorize that the amount of any such fee be charged to Deposit Account No. 12-2525.

Respectfully submitted,



Attorney for Appellant(s)

John P. Parise

(Reg. No. 34403)

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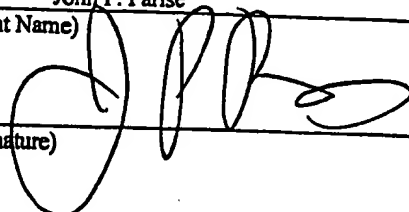
340 Kingsland Street

Nutley, New Jersey 07110

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CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being transmitted therewith) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner for Patents, Washington, D.C. 20231.

John P. Parise
(Print Name)

(Signature)

Date: February 28, 2001

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application:

Binggeli et al.

Group: 1613

Serial No. 08/711,339, filed September 6, 1996

Examiner: R. Ramseur

For: NOVEL PIPERIDINE DERIVATIVES HAVING RENIN INHIBITING ACTIVITY

STATUS INQUIRY

Nutley, New Jersey 07110
February 28, 2001

Commissioner for Patents
Washington, D.C. 20231

Sir:

Information regarding the present status of this application is respectfully requested.

Serial No. 08/711,339
Filed: September 6, 1996

Applicants' filed a PETITION TO INVOKE THE SUPERVISORY AUTHORITY OF THE COMMISSIONER UNDER 37 C.F.R. §1.181 mailed on March 27, 2000. Applicants have no record of any response communication from the Patent and Trademark Office and would appreciate knowing when a communication can be expected.

Respectfully submitted,



Attorney for Applicant(s)
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February 28, 2001

Dr. Richard Schwartz
Biotechnology Practice Specialist
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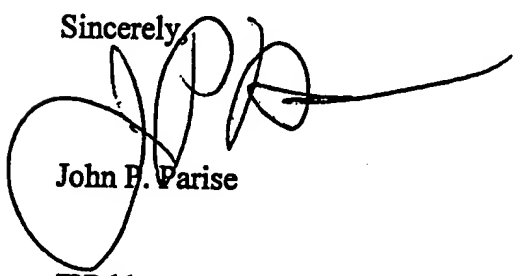
Re: U.S. Patent Application No. 08/711,339

Dear Dr. Schwartz:

Could you please follow-up on this patent application. We had addressed the Petition in the past, but have had no response for almost one year.

Thank you for any assistance you could provide.

Sincerely,



John P. Parise

JPP:bh
Enclosure
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